Validity and reliability of the Italian Constipation Assessment Scale.

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A Dal Molin, SC McMillan, F Zenerino, V Rattone, S Grubich, A Guazzini, L Rasero

Abstract

Constipation is a common problem among oncology patients and requires careful assessment. Use of validated instruments is important to improving its management. The aim of this study was to validate the Italian translation of the Constipation Assessment Scale (CAS). To test construct validity, patients and apparently healthy adults were asked to complete the CAS. The results indicated that there was a significant difference between the median CAS of the patient group and that of the apparently healthy group. Test–retest reliability was very high ($r=0.96$; $P=0.0001$), and the internal consistency as assessed by Cronbach's alpha was 0.768. These findings suggest that the Italian CAS can be used in clinical practice to document the presence and severity of constipation in cancer patients. However, further studies should be conducted in a larger sample of patients to confirm the results.

Key words: Constipation ● Nursing ● Cancer ● Palliative care ● Nursing assessment

The five most common symptoms in patients attended by palliative care services have been found to be pain, anorexia, constipation, asthenia, and dyspnoea, with one study reporting prevalences of 64%, 34%, 32%, 32%, and 31% respectively (Potter et al, 2003). Some of these symptoms, such as pain and dyspnoea, are more disabling than others; however, they may all adversely affect the person's quality of life (McMillan, 2002; Droney et al, 2008). Many studies indicate that constipation is a common problem among oncology patients (Droney et al, 2008; Bell et al, 2009; Brown et al, 2009) that correlates negatively with quality of life (Kyle, 2007). Constipation has various symptoms, such as headache, fatigue, abdominal swelling, and colic, and if not adequately managed can lead to disabling complications (Kyle, 2007). Improving quality of life while preventing the occurrence of certain disease states has become an increasingly important target in health promotion (World Health Organization, 1998).

Patients and clinicians often use different definitions of constipation (McCrea et al, 2008). Some patients think they are constipated if they do not have a bowel movement at least every day, whereas others think that the threshold is three per week (McMillan, 1999). Even among clinicians there is no uniformity in the definition of constipation, and often there is a discrepancy between what patients and their doctors think (Herz et al, 1996). Expert groups have defined criteria that can help clinicians determine the presence of constipation (Longstreth et al, 2006) (*Box 1*). One definition provided in the literature is 'a decrease in the frequency of passage of formed stools and characterised by hard stools that are difficult to pass' (McMillan, 1999). In this definition the number of bowel movements is not the only essential indicator of the presence of constipation.

Constipation can be classified as primary, secondary, or iatrogenic. Primary or simple constipation is caused by reduced physical activity, inadequate intake of fluid or fibre in the diet, or inadequate privacy and time devoted to defecation. These situations lead to reduced motility and increased intestinal transit time of faecal material (Kyle, 2009). Secondary constipation results from pathological situations such as bowel occlusions, hypothyroidism, and other problems (Kyle, 2009). Iatrogenic constipation is caused by the administration of medications (Kyle, 2009), the most relevant for oncology patients being some chemotherapy drugs and opioids (Oestreicher, 2008). These drugs reduce peristalsis and increase the intestinal transit time of the stool. The risk of developing constipation increases with increasing doses of the drugs (Maguire et al, 1981).

One study estimated that, among patients admitted to hospice, constipation has an incidence of 70–100% and a prevalence of 24–84% (McMillan, 2002). Other studies have indicated that the constipation prevalence in patients with advanced cancer is 52% (Shoemaker et al, 2011). The McMillan (2002) study found that the constipation problem is often underestimated by doctors and nurses. Eighty four per cent of the hospice patients interviewed for this study reported that

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Box 1. ROME III criteria for defining functional constipation*

1. Must include two or more of the following:
- Straining during at least 25% of defecations
- Lumpy or hard stools in at least 25% of defecations
- Sensation of incomplete evacuation for at least 25% of defecations
- Sensation of anorectal obstruction/blockage for at least 25% of defecations
- Manual manoeuvres to facilitate at least 25% of defecations (e.g. digital evacuation, support of the pelvic floor)
- Fewer than three defecations per week

2. Loose stools are rarely present without the use of laxatives

3. There are insufficient criteria for irritable bowel syndrome

*Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis (Longstreth et al, 2006)

Table 1. Constipation Assessment Scale

Item	No problem	Some problem	Severe problem
Abdominal distention or bloating	0	1	2
Change in amount of gas passed rectally	0	1	2
Less frequent bowel movements	0	1	2
Oozing liquid stool	0	1	2
Rectal fullness or pressure	0	1	2
Rectal pain with bowel movement	0	1	2
Small stool size	0	1	2
Urge but inability to pass stool	0	1	2

they were suffering from constipation symptoms, but only 29% of cases were reported in medical and nursing records (McMillan, 2002).

Aggressive management of constipation symptoms is essential to improving quality of life, but achieving this requires adequate identification of the problem. Use of rating scales is recommended in order to standardise the constipation measurement and develop adequate bowel management. Zernike et al (1999) underscore the effectiveness of the introduction of the risk assessment scale in bowel management and education programmes.

The Constipation Assessment Scale (CAS) has been studied in adult cancer patients (McMillan and Williams, 1989), paediatric patients (Woolery et al, 2006), and pregnant women (Broussard et al, 1998). The present paper describes the process of Italian validation of the CAS, in particular assessments of its construct validity and sensitivity. The reliability of the instrument was also analysed.

Constipation Assessment Scale

The CAS (*Table 1*) was developed for assessing individuals at risk of constipation as a result of receiving treatment for cancer (McMillan and Williams, 1989). It includes eight items, each of which is self-rated by the patient as 'no problem' (score of 0), 'some problem' (score of 1), or 'severe problem' (score of 2). The item ratings are then summed, so the overall score may range from 0 (no constipation) to 16 (worst possible constipation) (McMillan, 2002). The CAS thus allows the clinician to determine the presence and intensity of constipation.

The scale was designed and tested in Florida (McMillan and Williams, 1989). The known-groups technique was used to test the validity of the scale and a significant difference was found between patients receiving medications that cause constipation and a group of apparently healthy adults. The sensitivity of the CAS was supported in that it was able to differentiate between patients receiving opioids and those receiving vinca alkaloids. Strong evidence of test–retest reliability (r=0.98) was found and the internal consistency as assessed with alpha coefficients was acceptable for such a short scale (McMillan and Williams, 1989; McMillan, 2002).

Woolery (2006) also used the CAS with 21 paediatric oncology patients, testing its construct validity by comparing the mean CAS scores of subjects previously designated as not constipated with those of patients designated as constipated ($P<0.001$). Test–retest reliability was strong (r=0.93) and the scale demonstrated satisfactory internal consistency.

Finally, Broussard (1998) tested the CAS with pregnant women, modifying the scale from three points to five. Test–retest reliability was good (r=0.84–0.92), as was the internal consistency (alpha coefficient=0.82). There was a significant correlation between the dose of constipating medications ingested and the CAS score.

Research questions

- Is the Italian translation of the CAS valid for assessing the presence and severity of constipation?
- Is the Italian CAS reliable in assessing the presence and severity of constipation?

Methods

Design

This was a cross-sectional study, with the data being collected at a single point in time.

Setting and sample

The study was conducted in the palliative care service of Biella Hospital, Italy, which provides home-based care to patients at the end of their lives. The sample consisted of two groups: one

group of palliative care patients and another group of apparently healthy adults. The eligibility criteria for the first group were advanced cancer patient, ≥18 years old, and able to understand and provide consent for participation. The patients were recruited for the study by nurses or doctors on the palliative care staff who had previously been trained in data collection. On recruitment, the subjects received thorough information about the study and provided informed consent. Potential participants were informed that non-participation would have no consequences for their care. The group of apparently healthy adults consisted of nurses recruited by the first author (ADM).

The instrument

The CAS was translated from English to Italian by two people proficient in both languages and then clarified by the first author. Back-translation was then performed by the midwife member of the *Associazione Italiana Traduttori e Interpreti* (Italian Professional Association of Translators and Interpreters). The translation from English to Italian was discussed with the author of the CAS (SCM). She confirmed that the Italian version of the CAS was unaltered from the original scale. Face and content validity were assessed by a group of nurses with experience in the care of advanced cancer patients.

Data collection

Construct validity and reliability were tested following patient recruitment by recording the patients' personal and clinical data (date of birth, sex, current job, qualification, type of cancer, current therapeutic regimen, information about constipation) and asking them to complete the CAS. The same procedure was followed with the group of apparently healthy adults. A subgroup of these were then asked to complete the CAS again after approximately 1 hour to ascertain its test–retest reliability.

Data analysis

The demographic data was analysed using descriptive statistics. Construct validity was assessed by applying the Mann-Whitney test to the difference between the two groups' median CAS scores (McMillan and Williams, 1989). A significant difference may be taken as evidence of construct validity. The sensitivity of the scale was assessed using the Mann-Whitney test to compare the CAS scores of the subjects that had a condition or were taking medications with a risk of associated constipation with those of other patients who did not and were not.

Table 2. Sample demographics

	Patients (*n*=35)	Apparently healthy adults (*n*=73)	*P*
Mean age in years (SD)	76.8 (10.9)	44.5 (8.3)	<0.0001
Gender	60% male	9.6% male*	<0.0001

*In 1 case data not available. SD, standard deviation.

Table 3. Comparison of the group scores on the Italian version of the Constipation Assessment Scale (CAS)

	Patients (*n*=35)	Apparently healthy adults (*n*=73)	*P*
Median CAS score (range)	4 (0–13)	1 (0–10)	<0.0001

Differences between the qualitative data were assessed using the chi-squared test. To ascertain a measure of the test–retest reliability, the two CAS scores of the group of apparently healthy adults were correlated using a Pearson correlation coefficient. A correlation is assessed as being very low or absent if r is 0–0.25, low if r is 0.26–0.49, moderate if r is 0.50–0.69, high if r is 0.70–0.89, and very high if r is 0.90–1.00. In addition, inter-item correlations and Cronbach's alpha were used to investigate the tool's internal consistency.

The data were stored in a Microsoft Access 2000 database and analysis was performed with MedCalc version 10.3.2.0 and with STATA Statistical Software.

Ethical considerations

Permission was obtained to use the CAS for the study. Authorisation for the study was granted by the local research ethics committee before the study began. Usual patient care was not modified for the study and the data is presented without any reference to individual patients.

Results

Thirty five oncology patients and 73 apparently healthy adults participated in the study (*Table 2*). Thirty four of the patients had solid cancer and the remaining patient had haematological cancer. There was a significant difference between the median CAS scores of these two groups: the patients' median score was 4 whereas the apparently healthy group's median score was 1 ($P<0.0001$) (*Table 3*).

Of the various items in the patient group, the problem 'urge but inability to pass stool' received the highest rating for the group as a whole, followed by 'abdominal distention or bloating'. 'Rectal pain with bowel movement' received the lowest rating.

Table 4. Inter-item correlation matrix

	Abdominal distention or bloating	Change in amount of gas passed rectally	Less frequent bowel movements	Oozing liquid stool	Rectal fullness or pressure	Rectal pain with bowel movement	Small stool size	Urge but inability to pass stool
Abdominal distention or bloating	1.000	0.590	0.324	0.432	0.283	0.109	0.182	0.286
Change in amount of gas passed rectally	0.590	1.000	0.154	0.185	0.258	0.165	0.072	0.239
Less frequent bowel movements	0.324	0.154	1.000	0.478	0.439	0.113	0.331	0.324
Oozing liquid stool	0.432	0.185	0.478	1.000	0.232	0.180	0.231	0.429
Rectal fullness or pressure	0.283	0.258	0.439	0.232	1.000	0.551	0.068	0.439
Rectal pain with bowel movement	0.109	0.165	0.113	0.180	0.551	1.000	0.203	0.588
Small stool size	0.182	0.072	0.331	0.231	0.068	0.203	1.000	0.279
Urge but inability to pass stool	0.286	0.239	0.324	0.429	0.439	0.588	0.279	1.000

Eighty per cent (28) of the patients had CAS scores greater than or equal to 2—a cutoff used by Macmillan in her 2002 study—as opposed to only 41.1% (30) of the apparently healthy subjects (P=0.0003).

In the patient group, 20 subjects had a condition or were taking medications (opioids) with a risk of associated constipation, while the remaining 15 did not and were not. The median CAS score was 5 (range 0–13) in the first group and 3 (range 0–8) in the second (P=0.0791).

A subgroup of 34 of the apparently healthy subjects was asked to fill out the CAS again after a delay of approximately 1 hour. The correlation between these scores was 0.96.

Internal consistency as measured by Cronbach's alpha was 0.768 (*Table 4*). The mean inter-item correlation was 0.292 and correlations ranged between 0.068 and 0.590. All correlations were positive and the highest correlation was between 'abdominal distention or bloating' and 'change in amount of gas passed rectally'.

Discussion

Assessment of constipation is essential for improving its management, and use of validated instruments is very important (O'Mahony et al, 2001). In agreement with research carried out by the author of the scale (McMillan and Williams, 1989), the statistically significant difference found here in the median CAS scores of the patient group and the apparently healthy group supports the construct validity of the translated instrument. The construct validity is further supported by the difference found between the patients with a constipating condition or receiving constipating medications and those without and not. This finding suggests that the instrument can be used to indicate the severity of constipation. However, this difference was not statistically significant and this point should be further explored in future studies with a larger sample size.

The patient group was significantly older than the group of apparently healthy adults and was also found to be more constipated. This is in line with the literature, as the degree of constipation in the general population has been found to increase with age (Chiarelli et al, 2000).

The Italian version of the CAS showed very high test–retest reliability. Similar results have previousy been found in studies with advanced cancer patients (McMillan and Williams, 1989), pregnant women (Broussard, 1998), and paediatric oncology patients (Woolery, 2006). These data indicate the absence of ambiguous questions or varying interpretations from patient to patient. However, test–retest reliability should also now be studied in patient rather than apparently healthy groups.

The internal consistency was very acceptable for such a short scale (alpha coefficient=0.768) and was similar to that highlighted by McMillan and Williams (1989) (alpha 0.70) and Broussard (1998) (alpha 0.82).

Clinical implications and future directions

According to the Oncology Nursing Society, constipation is a Nursing-Sensitive Patient Outcome (Given et al, 2004)—that is, an outcome that is significantly affected by nursing interventions (Gobel et al, 2006). Prevention and management of constipation should therefore be essential components of oncology nursing practice (Woolery et al, 2008). Early identification of the problem is crucial, and constipation can be prevented through dietary modifications, increasing fluid intake, educating patients about pharmacological interventions, encouraging physical activity, and ensuring private time for defecation (Cope, 2001; Woolery et al, 2008).

It is important to know how serious the constipation problem is in people affected by cancer in order to promote educational prevention programmes and for the provision of information to patients and their families. However, the literature suggests that nurses do not always gather information about the constipation problem as they should (McMillan, 2002) and that there is a gap between symptoms and treatment decisions (Friedrishen et al, 2004).

The results of the present study suggest that the Italian CAS can be used in clinical practice to document the presence of constipation in cancer patients. The strengths of the tool are its simplicity, the speed with which it can be completed, and the fact that it can be completed by the patients themselves, which affords them greater privacy. Weaker patients who have difficulty self-reporting can complete the CAS with the aid of a nurse, but further investigation is needed into the validity and reliability of this approach. Further studies should also be conducted to confirm the validity and sensitivity of the Italian CAS with a larger sample of patients. In addition, the criteria for defining functional constipation (ROMA III) should be correlated with the CAS score.

Conclusion

Assessment of constipation in cancer patients is essential for improving its management. The results of this study provide evidence that an Italian version of the CAS instrument is valid, consistent, and reliable and would be of value in clinical practice. However, further confirmation is required, and evaluation by the nurse or doctor remains necessary for completing the clinical picture. IJPN

Acknowledgments
The authors wish to thank the Biella Hospital palliative care team and Dania Brioschi for her support in the translation.

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